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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,823	07/22/2003	Alastair McIndoe Hodges	104978-5(LFS198USACON1)	6567

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LIFESCAN/NUTTER MCCLENNEN & FISH LLP
155 SEAPORT BOULEVARD
BOSTON, MA 02210-2604

EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
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1795

NOTIFICATION DATE	DELIVERY MODE
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01/05/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary

Application No.

10/624,823

Applicant(s)

HODGES ET AL.

Examiner

ALEX NOGUEROLA

Art Unit

1795

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/981,385.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6/05/2008.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed October 24, 2008 ("Response") have been fully considered but they are not persuasive. Applicant argues
 - a) "... the Cottrell current, which White relies upon, is not capable of allowing both the diffusion coefficient and the concentration of glucose to be determined independently";
 - b) "The Examiner's arguments also fails to account for the fact the both Denuault and Daruházi teach methods that generate **non-** Cottrell currents."

See page 3 of the Response.

With regard to the first point the Examiner relied on Denault and Daruházi for teaching how to obtain the diffusion coefficient independently of current, not just Diebold and White.

With regard to Denuault Applicant more particularly states, “The teachings of Denuault are directed to microdisk and microsphere electrodes, not planar electrodes, i.e., the types of electrodes taught by Diebold. A person having ordinary skill in the art would recognize that the microdisk and microsphere electrodes disclosed in Denuault are actually the source of the non-Cottrell behaviors exhibited by its device.” See page 4 of the Response. The microdisk electrode of Denuault is encased in glass (bottom of page 28, bridging to page 29). One with ordinary skill in the art would then recognize that only one flat surface of the microdisk electrode is exposed to the electrolyte. The Examiner is not aware of any requirement that a planar electrode must have a square or rectangular shape. Thus, this microdisk electrode is effectively a planar electrode or at least a type of planar electrode.

As for Denuault’s microdisk electrode exhibiting non-Cottrell behaviors and so not being compatible with Cottrell current calculations, this comment is puzzling to the Examiner. The first term in the basic equation for current for the microdisk electrode used by Denuault (eqn. 3) is the standard Cottrell expression. Indeed, Denuault identifies it as such. See page 30 (“... obeys the Cottrell equation [1] (first term in eqn. 3).”). The second term is just a correction factor for the round shape of the microdisk electrode. A different second term is used if the electrode is spherical (eqn. 2). Presumably, for a “planar” electrode (that is a square or rectangular planar electrode) a second term would not be needed or yet another second term would be used. *In fact, this second term further shows the compatibility of Denuault with Diebold and White as it teaches improving the accuracy of the Cottrell current calculated by*

Diebold as modified by White by adding a term to the Cottrell equation that accounts for the shape of the electrode. In any event, this second term is not a key aspect of how the diffusion coefficient, D , is independently calculated: "The procedure for the direct measurement of D involves recording an i - t curve with a microdisk electrode over a time window which spans the transient and steady state regions." See the bottom of page 29. One with ordinary skill in the art would expect $i_p(t)/i_{p,ss}$, where $i_p(t)$ is the Cottrell current for a "planar" electrode (" $i_p(t)$ " is not used by Denuault but used by the Examiner as a parallel to $i_d(t)$; presumably, $i_p(t)$ would be the unmodified Cottrell equation as used by Diebold modified by White). *Indeed, Denuault refers to a very short time region as a **Cottrell region**.* See the last paragraph on page 31. It is interesting that the Conclusion of the article makes no reference to the shape of the electrode, but stresses how the described method allows independent determination of D and n values. Thus, the calculations made by Denuault very much are compatible with Cottrell currents.

With regard to Daruházi Applicant asserts "... there can be no enhanced current response and no steady-state current achieved for a Cottrell response to occur because the Cottrell equation does not account for either an enhanced current or a steady-state current." See page 5 of the Response. Applicant does not elaborate as to why the Cottrell equation *should* account for either an enhanced current or a steady-state current. That it does not do so does not necessarily mean that an independently determined diffusion coefficient as found by the method of Daruházi could not be used with the Cottrell equation, especially since Figure 3 in White shows that the Cottrell

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current does reach steady-state and the electrode system in Daruházi is very similar to that used by Diebold and what is claimed in that includes two very closely spaced planar electrodes. Applicant is also vexed that Daruházi calculates δ . See the bottom of page 5 of the Response, bridging to page 6. δ represents the distance between the electrodes working and auxiliary electrodes. See the abstract. However, in a mass manufactured small-volume biosensor such as taught by Diebold one with ordinary skill in the art would expect that this distance would be predetermined and not subject to serious random variations. Daruházi, in fact, states, "These electrodes, serving as working and auxiliary electrodes, respectively, ... are separated by a **defined distance** δ with a spacer. In other words, δ should normally be known, but if it is not it could be determined by the methods of Daruházi.

For the reasons set forth above Applicant's arguments have been found unpersuasive and so the prior art rejections based on 35 U.S.C. 103 are maintained.

Status of the Rejections pending since the Office action of July 25, 2008

2. All of the prior art rejections based on 35 U.S.C. 103 are maintained.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because it depends from non-existing claim 0.

Final Rejection

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Alex Nogueroles/
Primary Examiner, Art Unit 1795
December 30, 2008